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Attorney Docket # 5403-2RCE

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Stefan Lukas et al.

Serial No.: 09/177,427

Filed: October 22, 1998

For: Taste Masked Pharmaceutical Compositions

Examiner: Gregory W. Mitchell

Group Art: 1617

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REPLY BRIEF

This reply brief is being filed in triplicate pursuant to the provisions of 37 CFR § 1.193 in order to respond to the Examiner's Answer mailed on October 3, 2005.

The Examiner sustains the rejection of claims 16-25 and 27-30 over Morella (CA 2068366) in view of Dogulas (U.S. Patent No. 5,635,200) and the rejection of claim 26 over Morella in view of Dogulas and further in view of either Lu (U.S. Patent No. 4,808,411) or Yajima (U.S. Patent No. 5,707,646) under 35 U.S.C. 103(a).

Applicants respectfully disagree with the Examiner's rejection for the reasons set forth in the Appeal Brief filed July 14, 2005 and the following comments in response to the Examiner's Answer dated October 3, 2005.

First, the present invention provides a composition with an acceptable or desirable release rate, e.g., 8% release rate over 40 minutes, as shown by paragraph 13 of the Declaration previously submitted with the Appeal Brief ("the Declaration"), a result that is unexpected to a person of ordinary skill based on the teachings of Morella and Douglas. In contrast, the composition as disclosed by the primary reference Morella suffers from an unacceptable release rate, e.g., 30% in Example 1 and 18% in Example 5 over 40 minutes. The secondary reference, Douglas, does not discuss sustained release of a composition, much less the beneficial use of

spherical particles for a desirable sustained release rate. Assuming *arguendo* that a person of ordinary skill in the art might expect that the use of an aspect ratio of less than 3 is beneficial for masking taste of a pharmaceutical composition, he or she would not know that an acceptable or desirable release rate would be obtained by such use. Hence, the unexpected result regarding the desirable sustained release rate of the composition in accordance with the present invention further supports the position that the present invention is not obvious over Morella and Douglas. See e.g., MPEP 716.01(a).

Alternatively, a person of ordinary skill in the art would not expect the success of the present invention by combining the teachings of Morella and Douglas. As required under MPEP 2142 and 2143.02, to establish a *prima facie* case of obviousness, "there must be a reasonable expectation of success." Here, Morella does not teach a sustained release formulation comprising less than 23% polymer coating with an acceptable release rate. Neither does Douglas provide any instruction regarding a sustained release formulation. Hence, a person of ordinary skill in the art would not *reasonably* expect the success of the combination of the teachings of Morella and Douglas as proposed by the Examiner to make a sustained release formulation with acceptable release rate. This will instead discourage a person of ordinary skill in the art to combine the teachings of Douglas and Morella as proposed by the Examiner to arrive at the present invention.

Second, the Examiner's conclusion of obviousness of the present invention is based on improper hindsight reasoning or "obvious to try" rationale. See MPEP 2145 X.A and MPEP 2145 X.B. It is well-settled law that "It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious." See e.g., *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir., 1992; *Ecolchem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (quoting *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988)). The courts have repeatedly stated: "one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.*

Here, Morella does not teach or suggest any desirability of the use of less than 23% of the coating. The Examiner infers or picks from the broad teaching of the amount of coating of 10-80% and 28% from an example that Morella teaches the coating amount of less than 23%. Likewise, the Examiner concludes that Morella teaches the aspect ratio of less than 3 because Morella teaches 0.1-250 microns as the particle size and 0.005-25 microns as the thickness. Again,

without being provided any specific guidance or instruction, how would a person of ordinary skill in the art reasonably know the aspect ratio of less than 3 and any advantage therefrom? Therefore, it is inevitable that the Examiner's conclusion is based on the hindsight review of the present invention by piecing the prior art teachings together.

Furthermore, as discussed in our previously submitted Appeal Brief, a large number of process parameters in making the coated particles are involved. However, Morella does not provide any guidance as to which parameter is critical to obtain an acceptable taste masking and sustained release composition. Nor does Douglas teach how to remedy the deficiency of Morella to ensure the manufacture of a composition with an acceptable taste masking *and* sustained release rate. To arrive at the present invention from Morella and Douglas, a person of ordinary skill in the art would have to vary all parameters or try each of numerous possible choices until he could possibly arrive at a successful result. Therefore, it is "obvious to try" at most to modify the composition of Morella in combination with the disclosure of Douglas to arrive at the present invention. As discussed above, an "obvious to try" rationale is not a proper basis to reject the present claims 16-25 and 27-30.

Additionally, Morella does not fairly teach the aspect ratio of less than 3 by disclosing 0.1-250 microns as the particle size and 0.005-25 microns as the thickness even if the aspect ratio of less than 3 may be encompassed by all the possible choices of Morella as proposed by the Examiner. It is well settled law that just like disclosure of a genus may not fairly disclose a species encompassed by the genus, disclosure of a broad range without "sufficient specificity" may not teach a narrow range encompassed by the broad range. See. e.g., MPEP 2131.02 and 2131/03.

Therefore, claims 16-25 and 27-30 are not obvious under 35 U.S.C. 103(a) over Morella in view of Douglas.

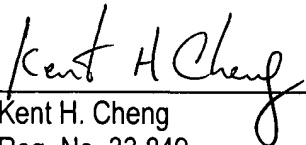
Claim 26 depending from claim 16 further recites that the pharmaceutically active compound is clarithromycin. To reject this claim as being obvious, the Examiner further cites to Yajima and Lu in combination with Morella and Douglas. As stated in the Examiner's Answer, Yajima and Lu are only relied on to show that it is desirable to mask the taste of and achieve the sustained release of clarithromycin. Neither of these two additional references remedies the deficiency of Morella and Douglas discussed above in connection with claims 16-25 and 27-30. For at least the same reasons discussed in connection with claims 16-25 and 27-30, claim 26 is not

obvious under 35 U.S.C. 103(a) over Morella in view of Dogulas and further in view of either Lu or Yajima.

For the foregoing reasons, it is respectfully submitted that appellant's claims are not rendered obvious by the cited references and are, therefore, patentable over the art of record, and the Examiner's rejections should be reversed.

Respectfully submitted,

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